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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,491	03/12/98	SCHWABE	C 07842.047.99

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HM22/1206

EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

19

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/041,491

Applicant(s)
Schwabe et al.

Examiner
ANISH GUPTA

Group Art Unit
1653



☒ Responsive to communication(s) filed on Sep 20, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The amendment filed 9/28/00 has been acknowledged. The amendment canceled claims 1-20 and added claims 21-28. Claims 21-28 are now pending.

2. All rejections made in the previous office action and not cited herein are hereby withdrawn.

Claim Rejections - 35 USC § 112
First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3 Claims 21-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous office actions, rejection claim and the reasons set forth below.

Applicants state that the specification has provided guidance as to the binding of the relaxin like factor to relaxin receptors. "Further, applicants have described and those skilled in the art are aware of conditions under which a protein such as relaxin like factor can be allowed to result in the activation of receptors." Applicants further contend "[t]he precise effect of the relaxin like factor in treating an organism such as a mammal has not and need not be focused on in the claims of the present application.

Applicant's arguments filed 9-20-00 have been fully considered but they are not persuasive.

The claims have been amended to be drawn to "a method comprising: administering to an organism expressing relaxin receptors, synthetic relaxin like factor". The claims do not specify any particular "method" for using relaxin like factor. The specification, however, states that the relaxin like peptide can be used in methods to treat various disorders such as neurodegenerative disorders, cardiovascular disease, and hair loss (see page 6 of the instant specification). Unlike Applicants contention, the claims would be inclusive of method of treating. Applicants have not

addressed any issues raised in the previous office actions with regards to enablement of treating disorders. Therefore the rejection is maintained.

New Grounds For Rejections

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a "a method comprising: administering to an organism expressing relaxin receptors, synthetic relaxin like factor". However, it is unclear what the method is intending to accomplish and therefore an endpoint cannot be ascertained. The claim is incomplete.

Claim 21 recites, "allowing the relaxin like factor to contact the receptor for a period of time and under conditions such as that the receptors are activity". The claim, as written, seem to imply that some method is involved to achieve the contacting to the receptor. However, unclear how such a step is achieved, beyond administration of the peptide.

In claim 25-26, the claims state that the organisms are sperms or cells. However, a cell, especially a sperm cell, is not known in the art as an organism.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipate by Bullesbach et al.

The claims are drawn to a method, by administering relaxin like factor.

Bullesbach et al. teach a method of administering relaxin like factor to a virgin female mice (see page 10612 and 10613). The mice were injected to subcutaneously with relaxin like factor to perform interpubic ligament assays (see page 16013, second column)). The reference also teach a receptor binding assay using iodo labeled relaxin like factor on tissues such as brain, uterus, skeletal muscle, kidney, and liver (see page 16014). The relaxin like co factor is obtained via Applied Biosystems peptide synthesizer (see page 16011). Since the reference teaches a method of administering relaxin like factor to a mammal, the claimed limitation are anticipated by the reference.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


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